

Claim

I. Claim 1: What I claim as my invention is for evenly spaced holes drilled or punched through/partially through all any composite layers and throughout the diabetic healing shoe insole, or removable cast walker insole, to reduce peak plantar foot pressure and shear stress. The shape of the holes can be round, square, oval, hexagon, octagon, or can have a smaller round/octagon diameter on one surface and a larger round/octagon diameter on the opposite surface. These holes, can be varied in sizes from 1/16" to 1/2" to accommodate different weight loading requirements, and are separated by at least 1/4" to 1" away from each others and in a square, round, hexagon, octagon, or alternating patterns.

When there is a focal point of pressure, the holes will be distorted or stretched to the direction of the pressure which will also allow the insole material to distorted or "give" resulting in reduction of the peak plantar pressure and the associated shear stress. This will also eliminate any pressure transferring problems as encountered in other insoles. Removing the pressure will allow the insole material to return back to the original state.

Test Results of the Peak Plantar Pressure of Various Insoles

We conducted a study to determine the plantar pressure under the medial forefoot and under the heel using:

1. Plain surgical shoe
2. Laminated insole with ¼" pink Plastazote and 1/8" PPT. This is the normal insole material for diabetic shoe.
3. Laminated insole with ¼" soft EVA for the bottom layer, ¼" pink Plastazote for the middle layer, and 1/8" Spenco for the top layer. One has no hole and another one has 3/16" holes drilled through all layers of the insole and are evenly spaced at ½".

The plantar pressures were measured using the F-Scan in-shoe pressure measurement system (TekScan, South Boston, MA). The test was performed on a treadmill at a walking speed of 1.5mph with a female subject weights 135lbs and wearing a surgical shoe with and without the insoles above. Data were collected and tabulated as follow:

Plain Surgical Shoe	Pressure
Pressure Under Medial Forefoot	15 psi (10.35N/Cm2)
Pressure Under Heel	20 psi (13.8N/Cm2)

Insole with PPT and pink Plastazote and surgical shoe

Number 1 Insole	Without Holes
Pressure Under Medial Forefoot	14 psi (9.66N/Cm2)
Pressure Under Heel	18 psi (12.42N/Cm2)

Insole with ¼” soft EVA for the bottom layer, ¼” pink Plastazote for the middle layer, and 1/8” Spenco for the top layer, and surgical shoe

Number 2 insole	Without Holes	With Holes
Pressure Under Medial Forefoot	13 psi (8.98N/Cm2)	10 psi (6.9N/Cm2)
Pressure Under Heel	17 psi (11.73N/Cm2)	15 psi (10.35N/Cm2)

As indicated in the tables above, the peak plantar pressure was further reduced by using insoles with evenly spaced holes.

Similar study conducted by Lavery LA and cohorts in “Reducing Dynamic Foot Pressures in High-risk Diabetic Subjects With Foot Ulcerations” (Diabetes Care 19(8):818-821, 1996) reports mean peak pressure for ulcers under the 1st metatarsal heads (medial forefoot) for the Total Contact Cast, DH Pressure Relief Walker (Royce Medical, Camarillo, CA), Aircast Pneumatic Diabetic Walker (Aircast, Summit, NJ), Extra Depth Shoe as 7N/Cm2, 8N/Cm2, 12.3N/Cm2, and 39.5N/Cm2 respectively.

Another study conducted by Armstrong DG and cohorts in “Total Contact Casts and Removable Cast Walkers” (J Am Podiatric Medical Association 89(1):50-53, 1999) reports peak plantar heel pressure for the Total Contact Cast, DH Pressure Relief Walker Aircast Pneumatic Diabetic Walker, and PW Minor Extra Depth Shoe (PW Minor and Son, Batavia, NY) as 18N/Cm2, 19N/Cm2, 20N/Cm2, and 25N/Cm2 respectively.

Comparing to the above studies for peak plantar pressure under the medial forefoot and the plantar heel, there is not a substantial difference between the new invention insole and the Total Contact Cast, which is a gold standard for offloading diabetic foot ulceration, to offload the medial forefoot (6.9N/Cm2 vs 7N/Cm2). However, the new insole is much better to offload the plantar heel pressure (10.35N/Cm2 vs 18N/Cm2).